510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Prepared	August 26th, 2011
Submitter Name	Mr. Kim Kuan LEE
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Device Trade Name	Swift™ FX Bella
Device Common Name/ Classification Name	Vented Nasal Mask; Accessory to Noncontinuous Ventilator (IPPB)
Classification	21 CFR 868.5905, 73 BZD (Class II)
Primary predicate device	Swift FX (K090244)
Description	The Swift FX Bella is a modified variant of the previously cleared Swift FX. It provides an interface such that airflow from a positive pressure source is directed to the patient's nose. The mask is held in place with adjustable headgear that straps the mask to the nasal nares. Swift FX Bella is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product. Swift FX Bella is a prescription device supplied non-sterile.
Intended Use	The Swift FX Bella channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system. The Swift FX Bella is: • to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed • intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.
Secondary predicate devices	Mirage Swift (K042403), Ultra Mirage II Mask (K050359), Mirage Quattro (K063122), Mirage Liberty (K063011), Mirage Micro (K072940), Swift LT (K073638)
Technological Characteristics comparison	*Comparison with primary predicate Swift FX (K090244)* The modified device and the primary predicate mask provide a seal via silicone interface. Both masks are offered in various sizes to ensure adequate fit over the extended patient population. Both masks incorporate vent holes to provide continuous air leak to flush out and minimize the amount of CO_2 rebreathed by the patient. The design of the mask components is such that the incorporation of these vent-holes does not interfere with the intended performance of the masks. Both masks connect to a conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors (ref: ISO 5356-1:2004)

Both masks are constructed using molded plastic and silicone components and fabric / nylon headgear. All the components of both masks are fabricated using materials deemed safe. (ref: ISO 10993-1).

Both the modified device and the primary predicate device are designed to operate on the same *Mirage* or *Swift* ResMed flow generator settings. The pressure-flow characteristics and flow impedance of both the modified device and the predicate device are identical.

Both the modified device and the primary predicate device can be reused in the home and hospital / institution environment.

Clinical Data

Use of vented nasal masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the modified Swift FX Bella, as was the case with the primary predicate Swift FX device.

Clinical studies confirmed that the Swift FX Bella met user requirements of comfort and stability. The CPAP seal performance is equivalent to the primary predicate device.

Performance Data

Comparison with primary & secondary predicates

The pressure-flow characteristics of the modified Swift FX Bella device is equivalent to the secondary predicate Mirage Swift (K042403).

The CO_2 performance of the modified device is equivalent to the secondary predicate Ultra Mirage II (K042403).

The STERRAD 100S and STERRAD NX reuse reprocessing performance is equivalent to the secondary predicates Mirage Quattro (K063122), Mirage Liberty (K063011) and Mirage Micro (K072940).

Silicone headgear material biocompatibility of the modified device is equivalent to the secondary predicate Swift LT (K073638).

Both the modified Swift FX Bella device and the primary predicate Swift FX device (K090244) are designed to operate on the same flow generator settings as specified in the User Guide.

Substantial Equivalence Conclusion

Modified Swift FX Bella is as safe and effective as the previously cleared predicate devices:

- it has the same intended use;
- it has identical technological characteristics to the previously cleared devices;
- the modified device did not raise any new questions of safety or effectiveness;
- it is at least as safe and effective as the previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Kim K. Lee
Regulatory Affairs Manager
ResMed Limited
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AUSTRALIA 2153

DEC - 7 2011

Re: K112489
Trade/Device Name: Swift™ FX Bella
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: November 4, 2011
Received: November 7, 2011

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety /ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: **Swift™ FX Bella**

Indication for Use

The Swift FX Bella channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Swift FX Bella is:

- to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.
- intended for single patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

Prescription Use ____X_____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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